

Record of Telephone Conversation, May 26, 2011 - LaViv

Submission Type: BLA Submission ID: 125348/0 Office: OCTGT

Product:
Autologous Cultured Fibroblasts

Applicant:
Fibrocell Technologies, Inc.

Telecon Date/Time: 26-May-2011 11:00 AM Initiated by FDA? Yes

Telephone Number:
Communication Category(ies):

1. Information Request

Author: DONALD FINK JR.
Telecon Summary:

Discussion regarding -----(b)(4)-----

Topic: CMC Post-marketing Commitment / LaViv / BLA STN BL 125348

FDA Participants:

Keith Wonnacott, Ph.D. / Branch Chief / CTB-DCGT-OCTGT
Kim Benton, Ph.D. / Deputy Director / DCGT-OCTGT
Donald Fink, Ph.D. / Consult CMC Reviewer / CTB-DCGT-OCTGT

Sponsor:

Dana Weinberger, Ph.D. / Sponsor Authorized Representative / CBR Intl Corp
Jeanne Novak, Ph.D. / CEO-President / CBR Intl Corp
John Maslowski, M.S. / VP-Operations, FIBROCELL
Karen Donhauser, Ph.D. / VP-Quality, FIBROCELL
Kevin Hennegan, MA / Senior Managing Consultant, CBR Intl Corp

----- (b)(4) ----- licensed product,
sponsor informed about alternative of ----- (b)(4) ----- data in
an annual report to the BLA as a post-marketing commitment. The sponsor provided oral agreement
to honor this commitment.

FDA asked sponsor, FIBROCELL, to submit, in writing, its agreement to honor a post-marketing commitment for submission of CMC information related to ----(b)(4)----- in Annual Reports to the BLA. Information pertaining to the following is to be provided:

1. -----(b)(4)-----
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2. -----(b)(4)-----

3. -----(b)(4)-----

Sponsor agreed to submit, in writing and in an expedited manner, its agreement to honor the CMC post-marketing commitment outlined.

Page Last Updated: 07/19/2011

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